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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/180,269	07/08/1999	KATHRYN LINDSAY BALL	CCI-007US	6599
959	7590	06/25/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			MURPHY, JOSEPH F	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/180,269

Applicant(s)

BALL ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12, 17, 44-47 and 51-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-12, 17, 44-47, 51-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

Claims 2-12, 17, 44-47, 51-59 are pending and under consideration.

Response to Amendment and Arguments

Applicant's amendment and arguments filed 3/24/2004 have been fully considered but they are persuasive in part, for the reasons set forth below.

The rejection of claims 2-12, 17, 44-47, 51-59 under 35 U.S.C. 103(a) as being unpatentable over WO 94/09135 (Beach et al.) in view of Xiong et al. (1993), for reasons of record set forth in Paper No. 21, 10/22/2002, has been obviated by Applicant's amendment and is thus withdrawn.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 4, 6, 10-12, 17, 44-47, 51-59 stand rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying a compound which decreases binding between p21 and cyclin D1, wherein the p21 fragment comprises SEQ ID NO: 2, 10, 28, 11 and 23, or wherein the p21 peptide fragment is 40 amino acids or less, and wherein the peptide fragment binds cyclin D1, and further wherein the cyclin D1 fragment binds p21, does not reasonably provide enablement for a method for identifying a compound which decreases binding between a peptide fragment of p21 comprising SEQ ID NO:

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4, 14 or xyLzF and a fragment of cyclin D1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, for reasons of record set forth in Paper No. 22, 4/22/2003, and the Office Action of 9/24/2003.

The rejection of record set forth that since the claims are drawn to methods using fragments of p21 and cyclin D1, insufficient guidance is provided to enable one of skill in the art to practice the claimed method because there is insufficient guidance as to which of the myriad of polypeptide species encompassed by the claim will retain the characteristics of p21 or cyclin D1. It would require undue experimentation for one of skill in the art to make and use the claimed polypeptides which are used in the claimed method, because for the fragments of p21 and cyclin D1, no function is set forth in the claims. Applicant argues that the term fragment as used in the presently amended claims is fully enabled; the present specification provides the information necessary for one of skill in the art to determine the peptide fragments that can be used in the claimed methods. There are two issues here, the first is that Applicant must teach how to make and use the invention. Here there is no use for a method using fragments of p21 that do not bind cyclin D1, nor is there a use for a method wherein the fragments of cyclin D1 do not bind p21. In order for the method to have a use, the fragments must bind to each other, therefore the claim needs to include the limitation wherein the fragments of p21 will bind cyclin D1 and wherein the fragments of cyclin D1 will bind p21. Furthermore, the second issue is that it would require undue experimentation to make fragments of p21 that do not bind to cyclin D1, or fragments of cyclin D1 which do not bind to p21, since there is no function set forth for the fragments. As set forth in the previous Office Action, it is known in the art that even single

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amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. Since the claims encompass p21 and cyclin D1 fragments with no functional limitation, and given the art recognized unpredictability of the effect of mutations on protein function, it would require undue experimentation to practice the claimed method.

Claims 2, 3, 4, 6, 10-12, 17, 44-47, 51-59 stand rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in Paper No. 22, 4/22/2003 and the Office Action of 9/24/2003. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The rejection of record set forth that Because of the use of the terms fragment in the claims, the claims encompass proteins having one or more amino acid substitutions, deletions, insertions and/or additions made to cyclin D1 or p21. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant

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number of structural differences between genus members is permitted. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, there is no function set forth for the fragments of p21 and cyclin D1, thus there is not written description for the fragments of p21 or cyclin D1 to be used in the claimed method because there is not a correlation between functional characteristics and structural features since there is not a function set forth.

Conclusion

Claims 2, 3, 4, 6, 10-12, 17, 44-47, 51-59 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
June 21, 2004



ELIZABETH KEMMERER
PRIMARY EXAMINER